PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jane P. Bearinger, et al.	Examiner: Gregory A. Anderson	
Serial No.:	10/781,582	Art Unit: 3773	
Filed:	02/17/2004	Attorney Docket: IL-11213	
TITLE:	**SYSTEM FOR CLOSURE OF A PHYSICAL ANOMALY**		

Honorable Commissioner for Patents
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANTS' BRIEF (37 C.F.R. § 1.192)

This brief is submitted in support of Appellants' Notice of Appeal from the Final Rejection mailed March 11, 2011 finally rejecting claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 of the subject application.

Appellants' notice of appeal was filed May 27, 2011.

One copy of the brief is being transmitted per 37 C.F.R. § 41.37.

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I. REAL PARTY IN INTEREST

The real party in interest is:

Lawrence Livermore National Security, LLC and the United States of America as represented by the United States Department of Energy (DOE) by virtue of an assignment by the inventors as duly recorded in the Assignment Branch of the U.S. Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

The application as originally filed contained claims 1-35.

The claims on appeal are claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35.

The status of all the claims in the proceeding (*e.g.*, rejected, allowed or confirmed, withdrawn, objected to, canceled) is:

Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 are rejected.

Claims 2, 3, 7, 8, 9, 10, 22, 23, 24, 26, 27, 28, 29, 30, and 33 are cancelled.

Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal are reproduced in the Appendix.

IV. STATUS OF AMENDMENTS

There are no amendments subsequent to the March 11, 2011 Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention provides an apparatus and a method for closure of a physical anomaly that forms a gap in a vascular wall. Appellants' invention provides a closure body made of a shape memory polymer (SMP) foam. The shape memory polymer (SMP) foam has at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above T_{trans} and the soft segment is formed at a temperature below T_{trans}. Appellants' invention is illustrated in FIGS. 1, 2, 3, and 5B reproduced below and described in the portions of the specification quoted below.

> The present invention provides apparatus and methods for closure of a physical anomaly. The closure is provided by a polymer body with an exterior surface. The exterior surface contacts the opening of the anomaly and closes the anomaly. The polymer body has a primary shape for closing the anomaly and a secondary shape that allows it to be positioned in the physical anomaly. (Page 7, Lines 22-26 of Appellants' Specification)

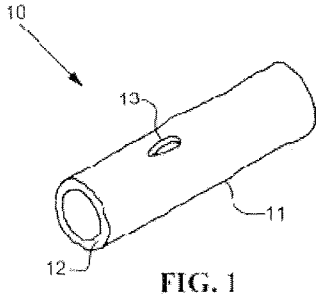


FIG. 1

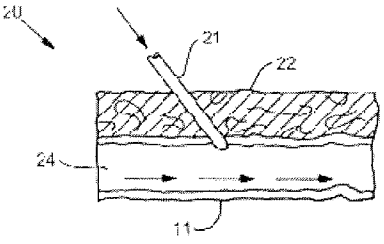


FIG. 2

FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, Lines 20-21 of Appellants' Specification) In order to close such sites, a closure body, in one embodiment a polymeric foam, is advanced to the puncture site in order to seal the site. (Page 9, Lines 5-6 of Appellants' Specification)

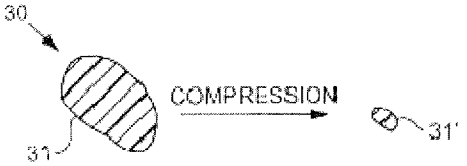


FIG. 3

FIG. 3 is a schematic of a closure body 31 in its expanded state and the closure body 31' in its compressed state. The closure body 31' is compressed to a smaller volume before deployment. (Page 10, Lines 15-17 of Appellants' Specification)

SMP foams comprise at least one hard segment and one soft segment. One segment contains a crosslinkable group; linking occurs via charge transfer, chemical or physical segment interactions. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment can return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, Lines 11-16 of Appellants' Specification)

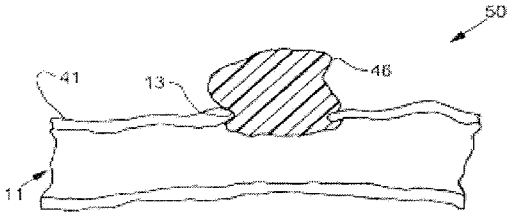


FIG. 5B

Full deployment of the SMP foam closure device is shown in FIG. 5B. The closure body 46 is shown in its expanded state (as opposed to compressed state) to fill the gap in the vessel wall in its entirety. In FIG. 5B, the puncture tract 45 is shown with the delivery catheter removed and with the closure body 46 in its expanded (actuated) state. (Page 13, Lines 24-26 of Appellants' Specification)

Appellants' independent claims 1, 19, and 32 involved in the appeal are "read on" Appellants' specification below. Portions of Appellants' specification are quoted and the paragraph containing the quote is identified by the page and line numbers.

Claim 1	Specification & Drawings
An apparatus for closure of a physical anomaly that forms a gap in a vascular wall, the apparatus comprising:	an apparatus for closure of a physical anomaly having a passage with the passage having an inner surface extending around the passage. (Page 4, lines 11-13) FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, lines 20-21)
a closure body, said closure body made of a shape memory polymer (SMP) foam,	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)

Claim 1 (Continued)	Specification & Drawings
said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall, and	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)

Claim 19	Specification & Drawings
A method of closing a physical anomaly that forms a gap in a vascular wall, the method comprising:	The present invention provides apparatus and methods for closure of a physical anomaly. (Page 7, lines 22-23) The embodiment 100, 100' can be used for the closure of punctures in vascular or non-vascular walls in the body. (Page 8, lines 7-8)
providing a closure body made of a shape memory polymer (SMP) foam,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)

Claim 19 (Continued)	Specification & Drawings
positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall, and	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly.	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

Claim 32	Specification & Drawings
A system for the closure of a physical anomaly that forms a gap in a vascular wall, the system comprising:	an apparatus for closure of a physical anomaly (Page 4, lines 11-12) FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, lines 20-21)
a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam,	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)

Claim 32 (Continued)	Specification & Drawings
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

Claim 32 (Continued)	Specification & Drawings
a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape; and	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2)
means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly.	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Final Rejection mailed March 11, 2011 states two grounds of rejection. The two grounds of rejection are summarized as follows:

Grounds of Rejection #1 - Claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans et al U. S. Patent No. 5,549,633 (hereinafter "Evans") in view of Bleys et al U. S. Patent No. 6,034,149 (hereinafter" Bleys"). The rejection is stated in numbered paragraph 2 on pages 3-5 of the March 11, 2011 Office Action.

Grounds of Rejection #2 - Claims 6, 13, and 15 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans in view of Bleys and further in view of Duane et al U. S. Patent No. 5,836,306 (hereinafter" Duane"). The rejection is stated in numbered paragraph 3 on page 5 of the March 11, 2011 Office Action.

VII. ARGUMENT

Argument Relating to Grounds of Rejection #1

The rejection in Grounds of Rejection #1 is respectfully traversed because Appellants' claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 are not obvious over the proposed combination of the Evan reference and the Bleys reference,

Legal Standard

> As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:
>
> Inquiry (A) - Determining the scope and content of the prior art; and
>
> Inquiry (B) - Ascertaining the differences between the claimed invention and the prior art; and
>
> Inquiry (C) - Resolving the level of ordinary skill in the pertinent art.
>
> The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness.
>
> Criterion 1 - The prior art reference (or reference when combined) must teach or suggest all the claim limitations.

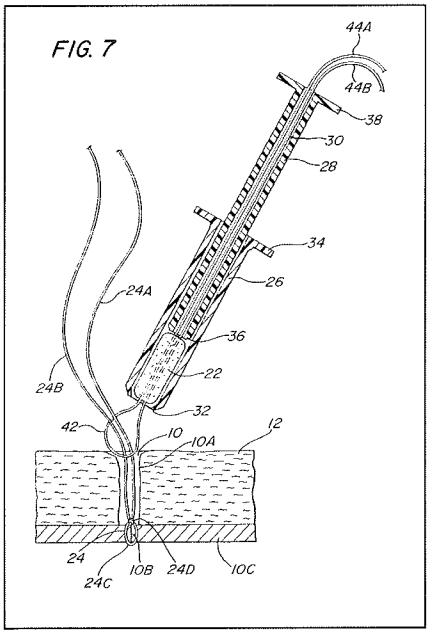
Criterion 2 - There must be a reasonable expectation of success with the proposed combination.

Criterion 3 - The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Inquiry (A) - Scope and Content of the Prior Art

The Evans Reference

The Evans reference is U. S. Patent No. 5,549,633 disclosing an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). The Evans device prevents blood seepage in the tissue outside the vascular wall and does not relate to the vascular wall itself. The Evans device is substantially different from Appellants' claimed invention which is "closure of a gap in a vascular wall." Appellants' claimed invention closes a physical anomaly that forms a gap in the vascular wall; whereas the Evans device is directed to the tissue outside the vascular wall. The Evans reference is illustrated in the drawing figures and described in the portions of the Evans reference reproduced below.

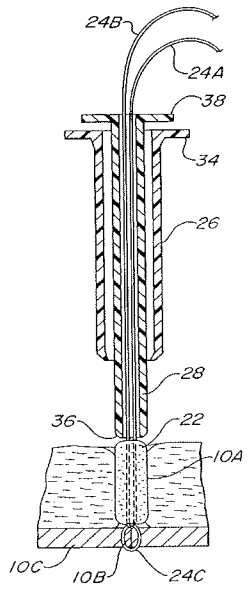


Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, there is shown at 20 one embodiment of apparatus constructed in accordance with this invention. The apparatus 20 is arranged to be used to apply a self-supporting mass or body of material 22, e.g., collagen like that disclosed in the aforementioned patent, to inhibit the flow of the fluid, e.g., blood, therethrough at or immediately adjacent a percutaneous puncture 10 (FIG. 7) which had been sealed or closed by some means located within the tract of the puncture to prevent the seepage of fluid from the puncture. In the embodiment shown in FIGS. 7-12 the apparatus 20 is shown applying that mass of material 22 into an arterial puncture tract 10A extending through the skin and underlying tissue 12 so that the mass 22 is adjacent the hole or opening 10B in the wall 10C of the artery. (Emphasis Added)

As will be appreciated from the discussion to follow the apparatus 20 is arranged to place the mass or body 22 either into the percutaneous puncture tract 10A or on the surface of the skin 12

above and contiguous with the puncture 10 to enable the mass to be secured in place in close engagement with the tissue of the puncture tract so that it reduces or prevents the seepage of a fluid from the puncture 10.

FIG. 10



The apparatus 20 is now ready to deploy the mass 22. To that end the user orients the apparatus so that the distal end 32 of the housing 26 is extended into the puncture tract 10A, like shown in FIG. 9. In this position the mass 22 is disposed immediately over the knot 24D. During the insertion of the distal end of the apparatus into the puncture tract the proximal portions 44A and 44B of the suture are pulled to make them somewhat taut. This facilitates the insertion procedure. Once the apparatus 20 is in position, the housing 26 is slid backward (retracted) with respect to the tamper 28 by squeezing their two flanged portions 34 and 38, respectively together, while holding the tamper 38 stationary. This action ejects the mass 22 into the puncture tract 10A, whereupon the mass is disposed immediately over the arterial wall, like shown in FIG. 10. (Emphasis Added)

The Bleys Reference

The Bleys reference is U.S. Patent No. 6,034,149 showing hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons. In general such absorbent articles are relatively voluminous; in particular diapers occupy a lot of space in shops and stores. It would be an advantage to reduce the volume of such absorbent articles without imparting the other properties."

Inquiry (B) - Differences Between Claimed Invention and the Prior Art

With regard to factual inquiry (B) ascertaining the differences between the claimed invention and the prior art, Appellants point out that Appellants' invention is very different from the apparatus and methods disclosed in the Evans and Bleys references.

The Evans reference is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). The Evans device is for preventing blood seepage in the puncture tract. First it is to be noted that the puncture tract is in the tissue

outside the vascular wall and is not in the vascular wall itself. The Evans device prevents blood seepage in the tissue.

Differences between Appellants' claimed invention and the Evans reference are illustrated by the side by side comparison of FIG. 5B from Appellants' application and FIG. 10 from the Evans reference provided below.

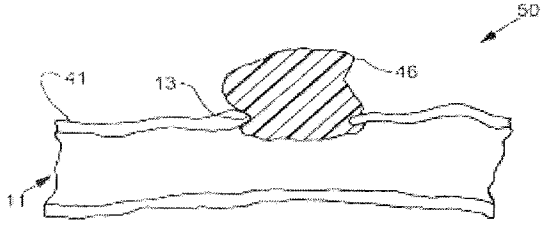
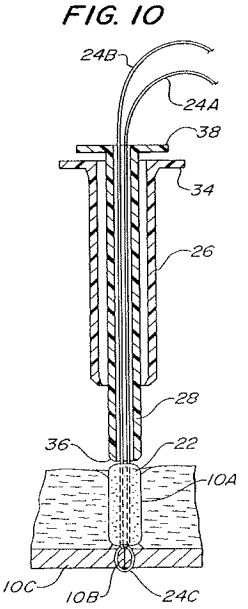


FIG. 5B
Appellants' Original Application



Evans Reference

The Evans device is substantially different from Appellants' claimed invention which is a method for the "closure of a physical anomaly that forms a gap in a vascular wall." Appellants' claimed invention closes a gap in the vascular wall; whereas the Evans device is directed to the tissue outside the vascular wall.

The Evans device is not in the vascular wall itself; whereas Appellants' claimed invention closes a gap in the vascular wall.

The Evans device prevents blood seepage in the tissue outside the vascular wall; whereas Appellants claimed invention closes the gap in the vascular wall. Note that there is no tissue in the "vascular wall."

The Bleys reference is entirely different from Appellants' claimed invention. Appellants' claimed invention closes a physical anomaly that forms a gap in a vascular wall; whereas the Bleys reference is directed to hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges,

wound dressings and tampons." The Bleys reference has nothing to do with Appellants' claimed invention

Inquiry (C) - Level of Ordinary Skill in the Pertinent Art

With regard to factual inquiry (C) resolving the level of ordinary skill in the pertinent art, Appellants point out that individuals working in the art are generally, engineers or scientists working in research or development.

Criterion 1 - References Do Not Teach All Claim Limitations

The criterion that prior art reference, or references when combined, must teach or suggest all the claim limitations is not met by the Evans and/or Bleys references or the Final Rejection. There are many of Appellants' claim limitations that are not taught or suggested by the Evans or Bleys references or by any combination of the Evans and Bleys references. Appellants will provide some unarguable examples of Appellants' claim limitations that are not taught or suggested by the Evans or Bleys references or by any combination of the Evans and Bleys references.

Claim 19

"A method of closing a physical anomaly that forms a gap in a vascular wall," or

"positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall," or

"transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly."

Claim 25

"The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger."

Claim 32

"A system for the closure of a physical anomaly that forms a gap in a vascular wall," or

"a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," or

> "a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," or
>
> "means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;" or
>
> "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

Note that Appellants' claim 19 includes the claim limitations: "positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall" and "transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly." The Evans reference clearly does not have these claim limitations because the Evans device is directed to the tissue outside the vascular wall and does not close the physical anomaly in the vascular wall defined by Appellants' claim limitations.

Note that Appellants' claim 32 includes the claim limitations: "means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;" and "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly." The Evans reference clearly does not have these claim limitations because the Evans device is directed to the tissue outside the vascular wall and does not close the physical anomaly in the vascular wall defined by Appellants' claim limitations.

Appellants note that there are many examples of Appellants' claim limitations that are not taught or suggested by the Evans or Bleys references or by any combination

of the Evans and Bleys references. For the sake of completeness Appellants are listing the claim limitations that are not taught or suggested by the Evans or Bleys references or by any combination of the Evans and Bleys references below.

Claim 1
"An apparatus for closure of a physical anomaly that forms a gap in a vascular wall,"

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,"

"said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall,"

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,"

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and
wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Claim 5
"The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall."

Claim 6
"The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."

Claim 13
"The apparatus of claim 1 wherein said delivery device includes a backbleed tube."

Claim 15
"The apparatus of claim 1 wherein said delivery device includes a delivery catheter, a plunger actuator, and a restraint tube."

Claim 17
"The apparatus of claim 1 including actuator means for controllably actuating said shape memory polymer (SMP) foam, said actuator means configured to transition said closure body from said reduced secondary shape to said primary shape by changing said temperature above T_{trans} by heating."

Claim 19
"A method of closing a physical anomaly that forms a gap in a vascular wall,"

"said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,"

"compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,"

"positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall,"

"transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly."

Claim 20
"The method of claim 19 wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system that uses light, coherent light, or heat."

Claim 21
"The method of claim 20, wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof."

Claim 25
"The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger."

Claim 31
"The method of claim 19 wherein the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof and wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in said arteriotomy puncture sites, septal defects, patent ductus, or combinations thereof."

Claim 32
"A system for the closure of a physical anomaly that forms a gap in a vascular wall,"

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,"

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,"

"said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall,"

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,"

"said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall,"

"means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;"

"means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

Claim 34
"The system for the closure of a physical anomaly of claim 32 wherein said shape memory polymer (SMP) foam of said closure body with a secondary shape for being positioned in the physical anomaly and a larger primary shape for closing said anomaly, said shape memory polymer foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} and wherein said means for transitioning said closure body changes said temperature above T_{trans} by heating."

Claim 35
"The system of claim 32 wherein said means for positioning said closure body in the physical anomaly in the vascular wall is a delivery catheter."

The combination of the Evans and Bleys references in the Final Rejection does not teach Appellants' claim limitations that have been identified and the combination of the Evans and Bleys references fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a). The rejection in Grounds of Rejection #1 should be reversed.

Criterion 2 - No Reasonable Expectation of Success

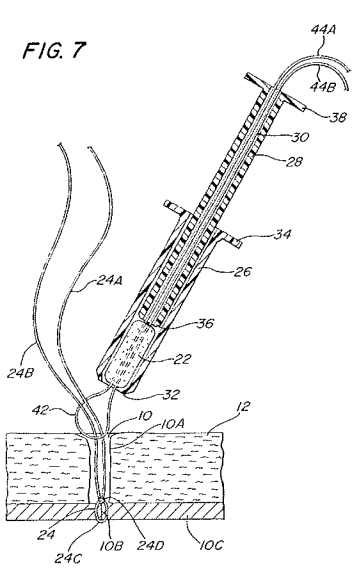
The criterion that there must be a reasonable expectation of success with the proposed combination is not met by the references or the Final Rejection. There could be no combination of the Evans reference and the Bleys reference that would provide a reasonable expectation of success or that would show Appellants' invention of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35.

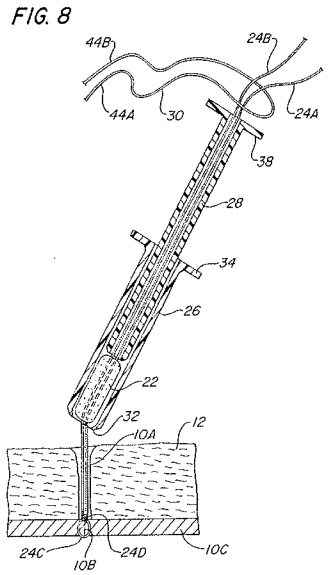
The Evans reference lacks Appellants' claim limitations "delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," "means for positioning said closure body in the physical anomaly in the vascular wall," and "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly." In the Evans reference Appellants' claim limitation "physical anomaly in the vascular wall" does not exist because in the Evans reference the anomaly or puncture has already been closed. Note the statement in the Evans reference: "percutaneous puncture 10 (FIG. 7) which had been sealed or closed by some means." (Column 5, lines 47-49 of the Evans Reference)

There is no possible combination of the Evans reference and the Bleys reference that would provide a reasonable expectation of success because the Evans reference lacks an "anomaly or puncture" and the Bleys reference has nothing to do with vascular walls.

The Evans reference requires a carrier filament 30 that basically comprises an elongated flexible member, e.g., a conventional suture, which is folded in two to form a looped distal end 42 and a pair of extending leg portions 44A and 44B. The loop 42 of the carrier filament 30 is adjacent to the puncture tract whereupon the extending portions 24A and 24B of the closure 24 are extended or passed through the interior of the loop. Once the extending portions 24A and 24B of the suture are passed through the carrier filament loop 42, the proximally extending portions 44A and 44B of carrier filament are pulled in the proximal direction. This action pulls the extending suture portions 24B and 24C through the passageway 40 of the mass 22, and through the interior of the tamper 28 until those extending portions are located proximally in the flanged end 38. The Bleys reference device would not work with a carrier filament 30 of the Evans reference.

The Evans reference requires that the loop 42 of the carrier filament 30 be anchored to the opening in the artery to pull the mass 22 into the percutaneous puncture tract 10A above the artery. This is illustrated in FIGS. 7 and 8 of the Evans reference reproduced below and described in Col. 7, lines 45-57 of the Evans reference reproduced below.





The apparatus 20 is held by the user so that the loop 42 of the carrier filament 30 is adjacent the puncture tract like shown in FIG. 7, whereupon the extending portions 24A and 24B of the closure 24 are extended or passed through the interior of the loop by any suitable means (not shown). Once the extending portions 24A and 24B of the suture are passed through the carrier filament loop 42, the proximally extending portions 44A and 44B of carrier filament are pulled in the proximal direction. This action pulls the extending suture portions 24B and 24C through the passageway 40 of the mass 22, and through the interior of the tamper 28 until those extending portions are located proximally of the flanged end 38, as shown in FIG. 8.

It would be impossible to place the mass 22 of the Evans reference in the opening in the artery because there is no place to anchor the loop 42 of the carrier filament 30 to pull the mass 22 into the opening in the artery. This is better understood with reference to FIG. 2 of Appellants' application reproduced below.

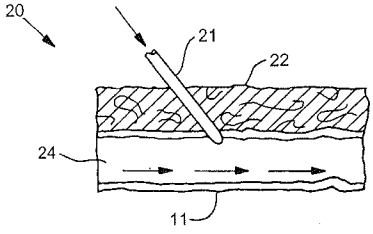


FIG. 2

As shown by FIG. 2 of Appellants' application above, there is no place to anchor a loop of a carrier filament to pull a mass into the opening in the artery as required by the Evans reference. Thus, the combination of the Evans and Bleys references in the Final Rejection fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31,

32, 34, and 35 under 35 U.S.C. § 103(a). The rejection in Grounds of Rejection #1 should be reversed.

Criterion 3 – No Reasons for Combining the References

The criterion that the Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007" has not been met. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination. The Evans reference is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). The Bleys reference shows hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons." There are no reasons for combining these two dissimilar systems.

The Final Rejection mailed March 11, 2011 does not provide any valid reasons for combining the references. In fact there are no valid reasons for combining the Evans reference and the Bleys reference in an effort to produce Appellants' claimed invention because the Evans reference lacks Appellants' claim of a "physical anomaly in the vascular wall." In the Evans reference the anomaly or puncture has already been closed. Note the statement in the Evans reference: "percutaneous puncture 10 (FIG. 7) which had been sealed or closed by some means." (Column 5, lines 47-49 of the Evans Reference) The Bleys reference is a hydrophilic flexible polyurethane foam "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons." and has nothing to do with vascular walls.

Further, a combination of the Evans reference and the Bleys reference would not show Appellants' invention of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35. Thus, the combination of the Evans and Bleys references in Grounds of Rejection #1 of the Final Rejection fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a) and the rejection should be reversed.

Arguments Relating to Grounds of Rejection #2

The rejection in Grounds of Rejection #2 is respectfully traversed because Appellants' claims 6, 13, and 15 are not obvious over the proposed combination of the Evans reference, the Bleys reference and the Duane reference.

Legal Standard

As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

> Inquiry (A) - Determining the scope and content of the prior art; and
>
> Inquiry (B) - Ascertaining the differences between the claimed invention and the prior art; and
>
> Inquiry (C) - Resolving the level of ordinary skill in the pertinent art.

The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness.

> Criterion 1 - The prior art reference (or reference when combined) must teach or suggest all the claim limitations.
>
> Criterion 2 - There must be a reasonable expectation of success with the proposed combination.
>
> Criterion 3 - The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Inquiry (A) - Scope and Content of the Prior Art

The Evans Reference is described above.

The Bleys Reference is described above.

The Duane Reference

The Duane reference (U.S. Patent No. 5,836,306) is an exchange accessory for use with a monorail catheter. The Duane reference is illustrated in FIG. 1 reproduced below and described in the portions of the Duane reference quoted below.

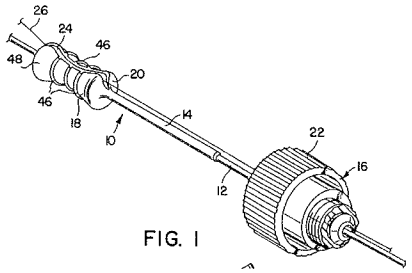


FIG. 1

"Referring now to FIG. 1, a preferred embodiment of the exchange accessory 10 is shown mounted on the proximal end of the shaft of a monorail catheter 12. The exchange accessory 10 includes a sleeve portion 14 that is adapted to be received in a connector 16 (shown broken away). The connector is conventionally mounted on the proximal end of a guide catheter (not shown) , external to the patient. The connector 16 may be, for example, a Tuohy-Borst connector or any suitable connector which permits axial positioning of the catheter 12 and permits introduction of a contrast medium or medicament through the guide catheter and into the patient's vascular system. In accordance with one aspect of the invention, the sleeve portion 14 has an internal diameter which is greater than and complementary with the external diameter of the shaft of the particular catheter 12. Thus, the sleeve portion 14 defines a space about the shaft of the catheter 12 sufficient to allow backbleed of blood therethrough in a controlled manner. To facilitate discussion, the shaft of the catheter 12 is more generally referred to as the catheter 12."

With regard to factual inquiry (B) ascertaining the differences between the claimed invention and the prior art, Appellants point out that the Evans, Bleys, and Duane references fail to teach the following limitations of Appellants' claims 6, 13, and 15:

Claim 6
"The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."

Claim 13
"The apparatus of claim 1 wherein said delivery device includes a backbleed tube."

Claim 15
"The apparatus of claim 1 wherein said delivery device includes a delivery catheter, a plunger actuator, and a restraint tube."

Inquiry (C) - Level of Ordinary Skill in the Pertinent Art

With regard to factual inquiry (C) resolving the level of ordinary skill in the pertinent art, Appellants point out that individuals working in the art are generally, engineers or scientists working in research or development.

Criterion 1 - References Do Not Teach All Claim Limitations

The criterion that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. With reference to the descriptions of

the Evans, Bleys, and Duane references above, it is clear that the references fail to teach the following limitations of Appellants' claims 6, 13, and 15:

> **Parent Claim 1**
> "An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," or
>
> "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or
>
> "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or
>
> "said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or
>
> "wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," or
>
> "wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."
>
> **Claim 6**
> "The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."
>
> **Claim 13**
> "The apparatus of claim 1 wherein said delivery device includes a backbleed tube."
>
> **Claim 15**
> "The apparatus of claim 1 wherein said delivery device includes a delivery catheter, a plunger actuator, and a restraint tube."

Thus, the combination of Evans, Bleys, and Duane references in the Final Rejection does not teach all of Appellants' claim limitations and the combination of Evans, Bleys, and Duane references fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a). The rejection in Grounds of Rejection #2 should be Reversed.

Criterion 2 - No Reasonable Expectation of Success

The criterion that there must be a reasonable expectation of success with the proposed combination has not been met. There could be no combination of Evans, Bleys, and Duane references that would provide a reasonable expectation of success or that would show Appellants' invention of claims 6, 13, and 15.

The Evans, Bleys, and Duane references fail to disclose Appellants' parent claim 1 limitations: "An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," "wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," "wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

The Evans, Bleys, and Duane references fail to disclose Appellants' claim 6 limitations: "The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."

Since these elements are missing from all three references, there could be no combination of the three references that would have reasonable expectation of success of providing Appellants' invention of claims 6, 13, and 15.

Thus, the combination of Evans, Bleys, and Duane references in the Final Rejecion fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a) and the rejection should be reversed.

Criterion 3 – No Reasons for Combining the References

The criterion that the Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007" has not been met. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed

combination. There could be no combination of Evans, Bleys, and Duane references that would show Appellants' invention of claims 6, 13, and 15.

The Evans reference is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). The Bleys reference shows hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons." The Duane reference is an exchange accessory for use with a monorail catheter. There are no reasons for combining these three dissimilar systems. Further, a combination of the Evans, Bleys, and Duane references would not show Appellants' invention of claims 6, 13, and 15.

Thus, the combination of Evans, Bleys, and Duane references in Grounds of Rejection #2 of the Final Rejection fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a) and the rejection should be reversed.

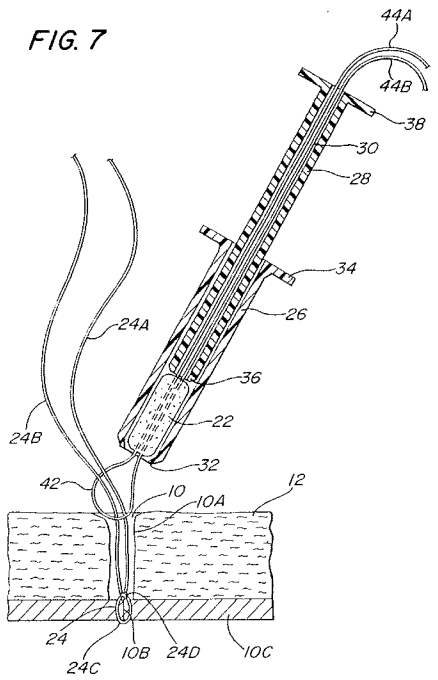
Errors in Final Rejection – Misinterpretation of Evans Reference

Appellants point out errors in the Final Rejection wherein the disclosure of the Evans reference is misinterpreted. The Final Rejection mailed March 11, 2011 in the paragraph that bridges pages 5-6 includes the following statements:

> "Applicant argues that Evans reference does not close a physical anomaly that forms a gap in a vascular wall. Examiner disagrees, while the foam of Evans et al. does not close the gap in the vessel, the Evans et al. device clearly does. The suturing aspect of the Evans et al. device pulls the vessel walls together and is subsequently sealed by the insertion of the foam member. Further, the device of Evans et al. is capable of being inserted within the vessel and if so placed would perform in the same manner as if it is placed slightly above the vessel in the overlying tissue as disclosed by Evans et al."

Appellants point out that in the Evans reference Appellants' claim limitation "physical anomaly in the vascular wall" does not exist because in the Evans reference the anomaly or puncture has already been closed. Note the statement in the Evans reference: "percutaneous puncture 10 (FIG. 7) which had been sealed or closed by some means." (Column 5, lines 47-49 of the Evans Reference)

Relevant portions of the Evans reference are reproduced below showing that the Evans reference lacks Appellants' claim limitation of a: "physical anomaly in the vascular wall."



Evans Reference

In the embodiment shown in FIGS. 7-12 the apparatus 20 is shown applying that mass of material 22 into an arterial puncture tract 10A extending through the skin and underlying tissue 12 so that the mass 22 is adjacent the hole or opening 10B in the wall 10C of the artery. (Emphasis Added) . (Column 5, lines 51-56 of the Evans Reference)

... percutaneous puncture 10 (FIG. 7) which had been sealed or closed by some means. (Column 5, lines 47-49 of the Evans Reference)

The Evans reference lacks Appellants' claim limitations "delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," "means for positioning said closure body in the physical anomaly in the vascular wall," and "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly." In the Evans reference Appellants' claim limitation "physical anomaly in the vascular wall" does not exist because in the Evans reference the anomaly or puncture has already been closed.

The combination of the Evans and Bleys references fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a). The rejection in Grounds of Rejection #1 should be reversed.

Errors in Final Rejection – Incorrect Interpretation of Claim Limitations

The Final Rejection contains an error in incorrectly interpreting claim limitations of Appellant's claims. The Final Rejection contains an error because it does not give effect to Appellants' specification and drawings in interpreting the meaning of the claim limitations: "delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," "means for positioning said closure body in the physical anomaly in the vascular wall," or "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

The Final Rejection contains an error because it does not give effect to Appellants' specification and drawings in interpreting the meaning of the first two claim limitations: "delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall" and "means for positioning said closure body in the physical anomaly in the vascular wall." Appellants' drawing FIG. 5B and Appellants' specification Page 13, Lines 24-26 are reproduced providing information for interpreting the meaning of these two claim limitations.

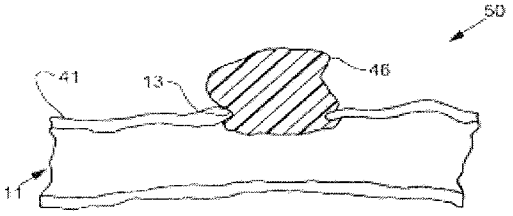


FIG. 5B

Full deployment of the SMP foam closure device is shown in FIG. 5B. The closure body 46 is shown in its expanded state (as opposed to compressed state) to fill the gap in the vessel wall in its entirety. In FIG. 5B, the puncture tract 45 is shown with the delivery catheter removed and with the closure body 46 in its expanded (actuated) state. (Page 13, Lines 24-26 of Appellants' Specification)

Drawing FIG. 5B shows the gap 13 in the vascular wall that is filled by the closure body 46. Appellants' claim limitation is a "delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall."

Appellants point out that the in the Evans reference Appellants' claim limitations "deploy said closure body into the physical anomaly in the vascular wall" and "means for positioning said closure body in the physical anomaly in the vascular wall" do not exist

because in the Evans reference the physical anomaly has already been closed. Note the statement in the Evans reference: "percutaneous puncture 10 (FIG. 7) which had been sealed or closed by some means." (Column 5, lines 47-49 of the Evans Reference)

The Final Rejection contains an error because it does not give effect to Appellants' specification and drawings in interpreting the meaning of the first two claim limitation: "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly." Appellants' drawing FIG. 3 and Appellants' specification Page 10, Lines 15-17 and Page 12, Lines 11-16 are reproduced providing information for interpreting the meaning of this claim limitation.

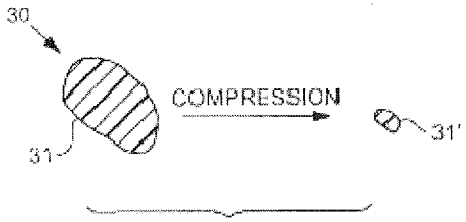


FIG. 3

FIG. 3 is a schematic of a closure body 31 in its expanded state and the closure body 31' in its compressed state. The closure body 31' is compressed to a smaller volume before deployment. (Page 10, Lines 15-17 of Appellants' Specification)

SMP foams comprise at least one hard segment and one soft segment. One segment contains a crosslinkable group; linking occurs via charge transfer, chemical or physical segment interactions. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment can return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, Lines 11-16 of Appellants' Specification)

Appellants point out that the in the Evans reference Appellants' claim limitation "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly" does not exist because in the Evans reference the physical anomaly has already been closed. Note the statement in the Evans reference: "percutaneous puncture 10 (FIG. 7) which had been sealed or closed by some means." (Column 5, lines 47-49 of the Evans Reference)

Appellants' specification and drawings should have been used to interpret the meaning of the claim limitations discussed above. Had Appellants' specification and drawings been correctly used to interpret the meaning of the claim limitations it would be clear that the Evans and Bleys references do not show these claim limitations. The combination of the Evans and Bleys references fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a). The rejection in Grounds of Rejection #1 should be reversed.

SUMMARY

Appellants have demonstrated that claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 are not obvious over the proposed combination of the Evans reference and the Bleys reference. The rejection in Grounds of Rejection #1 should be reversed.

Appellants have demonstrated that claims 6, 13, and 15 are not obvious over the proposed combination of the Evans reference and the Bleys reference and the Duane reference. The rejection in Grounds of Rejection #2 should be reversed.

It is respectfully requested that the rejections be reversed and claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal be allowed.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. An apparatus for closure of a physical anomaly that forms a gap in a vascular wall, the apparatus comprising:

a closure body, said closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall, and

a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,

wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and

wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.

4. The apparatus of claim 1 including actuator means for controllably actuating said shape memory polymer (SMP) foam having at least one hard segment wherein said

hard segment is formed at a temperature above T_{trans} by changing said temperature above T_{trans}.

5. The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall.

6. The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement.

11. The apparatus of claim 1 wherein said delivery device is a delivery catheter.

12. The apparatus of claim 1 wherein said delivery device includes a plunger actuator.

13. The apparatus of claim 1 wherein said delivery device includes a backbleed tube.

14. The apparatus of claim 1 wherein said delivery device includes a plunger actuator and a delivery catheter.

15. The apparatus of claim 1 wherein said delivery device includes a delivery catheter, a plunger actuator, and a restraint tube.

16. The apparatus of claim 1 wherein the physical anomaly is an arteriotomy puncture site.

17. The apparatus of claim 1 including actuator means for controllably actuating said shape memory polymer (SMP) foam, said actuator means configured to transition said closure body from said reduced secondary shape to said primary shape by changing said temperature above T_{trans} by heating.

19. A method of closing a physical anomaly that forms a gap in a vascular wall, the method comprising:

providing a closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall, and

transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly.

20. The method of claim 19 wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system that uses light, coherent light, or heat.

21. The method of claim 20, wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof.

25. The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger.

31. The method of claim 19 wherein the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof and wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in said arteriotomy puncture sites, septal defects, patent ductus, or combinations thereof.

32. A system for the closure of a physical anomaly that forms a gap in a vascular wall, the system comprising:

a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall,

a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,

said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall,

means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape; and

means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly.

34. The system for the closure of a physical anomaly of claim 32 wherein said shape memory polymer (SMP) foam of said closure body with a secondary shape for being positioned in the physical anomaly and a larger primary shape for closing said anomaly, said shape memory polymer foam having at least one hard segment and one

soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} and wherein said means for transitioning said closure body changes said temperature above T_{trans} by heating.

35. The system of claim 32 wherein said means for positioning said closure body in the physical anomaly in the vascular wall is a delivery catheter.

IX. EVIDENCE APPENDIX

There are no entries in the Evidence Appendix.

X. RELATED PROCEEDINGS APPENDIX

There are no entries in the Related Proceedings Appendix.